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Clinical Pharmacist-Led Oral Chemotherapy Adherence Programs among Patients with Breast Cancer: A Multicentric Study

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Abstract

Oral chemotherapy has brought a very positive shift in treating cancer; enabling home based treatment, however there are major issues of adherence and managing toxicity. The study was a multicentered, interventional research study to understand how therapeutic treatment adherence programs discussed by clinical pharmacists in three oncology centers in Switzerland, India, and South Africa yielded. One hundred and forty breast cancer patients with oral chemotherapy (capecitabine or palbociclib) were provided structured counseling with follow-ups every two weeks and the monitoring of adverse events during the 12 weeks. Toxicity and hospitalization data were used to measure clinical outcomes of safety, whereas the MMAS-8 scale and pharmacy refill reports were used to evaluate adherence. The outcomes were 22%-enhanced adherence scores (p < 0.001), less rare adverse events (Grade 3 or more ride), and improved patient satisfaction, with 87% of participants claiming that pharmacist assistance is an essential part of their treatment. Results highlight the importance of pharmacist-led interventions in safely, effectively and patient-centering oral chemotherapy management.

Keywords: oral chemotherapy, breast cancer, clinical pharmacist, adherence, monitoring toxicity, patient education, MMAS-8, oncology pharmacy, pharmacist intervention, global cancer care

1. Introduction

1.1 Background

Cancer therapies during the last twenty years have ushered in a paradigm change where conventional intravenous chemotherapy has given way to oral anticancer agents (OACAs). These treatments provide more convenience, less time spent in hospitals and more freedom to the patients receiving treatment. Oral chemotherapeutics in the management of the hormone receptor-positive disease stage and the metastatic disease stage such as capecitabine and palbocicline have become a commonality in the care of breast cancer patients. But, in the process, this transition has also increasingly put the ball of safe and effective therapy in the court of the patients themselves. Oral chemotherapy, unlike parenteral chemotherapy, is not treated under strict medical control, and the patient must independently comply with a complex and individual dosing pattern, cope with the side effects associated with it, and be able to realize possible signs of toxic effects. This has led to the realization that oral chemotherapy compliance is not only a clinical but also a behavioral problem therefore necessitating a more active and interdisciplinary mode of care.

1.2 Compliance issues in Oral Chemotherapy

Regardless of the increase in OACA utilization, non-adherence becomes a significant impediment to optimal clinical outcome achievement. Studies also show that as many as 30-40 percent of patients who undergo cancer treatment can be non-compliant with their oral chemotherapy treatments; by omitting doses, taking drugs out of regime, or just stopping. With breast cancer, in which long-term control of the disease and subsequent survival is conditional upon regular pharmacologic therapy, this trend is especially troubling.(1)

Poor adherence in the oral chemotherapy settings can be determined by several factors. First, the dosing regimens (with on/off cycles, dietary restrictions, regular dose modifications to account for toxicity) are very complex which poses the risk of errors. Second, nausea, hand-foot syndrome, neutropenia, and fatigue are adverse effects that may make the continuation unworthy of further assistance. Third, patients are not adequately educated and counseled on how to identify and deal with the side effects particularly where there is lack of access to oncology teams in places where care is fragmented.

Also, the psychosocial condition (e.g., emotional disturbance, financial load, and family inadequacy) may have influence on medication taking behavior. In contrast to the IV treatment performed in hospital setting where the control of administration and monitoring belong to the clinical staff, the oral regimens require more attention to

self-management and memory as the methods of administration and monitoring cannot be reduced to 24-hour cycle of administration and monitoring as is the case in an IV hospital setting.(2)

1.3 Objectives of the Study

Owing to the dire necessity of introducing systematic support systems that could augment adherence and safety when using oral chemotherapy, this study was based on a hypothesis that the introduction of general pharmacist-led interventions could change the perspective of experiments conducted on breast cancer patients regarding treatment adherence, the ability to manage treatments associated with toxicities, and patient-reported outcomes.

The initial aim of this multicentric interventional study was to observe whether the organized involvement of the pharmacist, including the provision of patient education and consistent follow-ups and side effect monitoring, was able to substantially enhance the rate of adherence to oral chemotherapy. Quantitative measure of adherence was determined by the Morisky Medication Adherence Scale (MMAS-8) and confirmed by the presence of pharmacy refills.

The secondary objectives were to determine the influence of the intervention on incidence and severity of adverse events of Grade 3 or higher, according to Common Terminology Criteria for Adverse Events (CTCAE), and to evaluate patient satisfaction with the model of the pharmacist-led care. The research study of three different oncology centers in Switzerland, India, and South Africa allowed the international view onto the viability and efficiency of pharmacist-mediated programs across healthcare systems with different levels of resources.

Finally, the study aims to offer empirical data to support the introduction of oncology pharmacists to the regular outpatient cancer care, especially in the scenarios where oral chemotherapy is concerned due to which the role of the oncology pharmacist can be instrumental in the process of filling the existing gaps between prescription and patient compliance.(3)

2. Oncology PLI

2.1 Function of Clinical Pharmacists in Management of cancer

Clinical pharmacists working in the oncology setting now utilise their expanded role in providing direct care to patients, medication therapy management, and interdisciplinary coordination as part of their portfolio rather than just the traditional role with medication dispensing. Pharmacists have an increasing role to play in the context of cancer treatment, especially with oral chemotherapy agents (OACAs) to support medication safety, optimal dosing schedules, adverse effect management, and even patient adherence.

Pharmacists have the potential to support oral chemotherapy due to excellent knowledge of pharmacokinetics, drug-drug interaction, and supportive care needs. This is particularly important in oral regimens, where self administration by the patient makes the healthcare system less responsible in the prescription as well as the accuracy and consistency. Through large-scale education on the right use of the drug, early manifestation of toxicity, management of symptoms, pharmacists step in to reduce clinical risks related to the use of self-administered chemotherapy at home.

The role of the clinical pharmacists is integrated into the treatment team and involved in tumor boards, drug regimen verification, dosing, and follow-up planning in most oncology centers across the world. Their intervention can also remarkably lessen unnecessary stays of the hospitalization given that they will directly look into root causes of noncompliance and discontinuation of drug treatment, common causes of which include hand-foot syndrome, neutropenia, and gastrointestinal toxicity.

2.2 Previous Adherence Programs Evidence

There have been previous studies with substantial evidence of the use of pharmacist led adherence programs in developing numerous chronic illnesses, such as HIV, hypertension, and diabetes. Oncology is one area where there is still inadequate use of structured adherence programs despite the increasing number of literatures confirming the effectiveness of these programs.(4)

A systematic review issued by Journal of Oncology Pharmacy Practice (2020), showed that adherence to oral chemotherapy may be boosted by 20-30% in terms of pharmacist-guided education and follow-up. In one randomized controlled trial of patients with chronic myeloid leukemia that received either pharmacist counseling monthly or remained a control group, the adherence was significantly higher in those patients who received pharmacist counseling at the second month, and toxic Grade 3 to 4 was low in the former in comparison to the control group.

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Moreover, telephone follow-ups by pharmacists have been specifically useful in strengthening medication routines, identifying initially any nonadherence symptoms, responding to patient questions in the real time. These programs have a low cost, easily scalable, and adaptable to different settings which are quite crucial in the setting of a resource-limited care environment.

Nevertheless, even with this evidence, adoption of such programs in regular oncology practice is irregular because of limited pharmacist labor force, a gap in outlining standardized procedures, and inadequate collaboration with oncologists and nursing groups. Looking at these barriers, they can be overcome with the help of specific institutional support and the cross-disciplinary acknowledgment of clinical value in pharmacists in the field of oncology.

2.3 Multicenter Implementation rationale

Since the demographics of patients, the state of health infrastructure, and the culture of patients in global oncology care are varied, conducting an implementation that involves multiple centers will help give a more detailed picture of the efficacy and flexibility of pharmacist-led adherence programs. It is a multinational study that covers three location countries, Switzerland, India, and South Africa, where the health systems play a different role in providing care, having in turn high resource, mixed, and resource limited systems accordingly.(5)

Switzerland offered a comparable benchmark of developed clinical pharmacy structures in the oncology clinics that directly compared to the sites in India and South Africa where such facilities are still developing or not yet routine. This research sought to investigate how the pharmacist-led program structure works due to varying restrictions, i.e. patient literacy, access to medication and clinicians per patient, in the three different centers.

Also through the multicenter approach was the ability to evaluate whether interventions were universal or contextual. As an illustration, of the several adaptations made (e.g., multilingual educational materials in India or simplified symptom grading tools in South Africa), it was implemented that structured counseling and telephonic follow-ups occurred in all sites, although these were not contextually necessary.

This is because this way of thinking internationally can allow the findings to be generalizable and can be applied in a wider range of breast cancer patients. More to the point, it confirms that the pharmacist-led adherence program is successfully customizable and adaptable to most diverse settings of health care facilitating and proving the point that it must be included as one of the universal elements of oral chemotherapy around the globe.

3. Design and Intervention Elements of Program

This multicenter trial introduced an oral chemotherapy adherence program structured by a pharmacist to resolve the identified obstacles to treatment adherence and toxicity that may take place. The model of intervention was created by collaboration of three oncology pharmacists in three participating centers, Switzerland, India, and South Africa, and in accordance with the international best practice. This program was 12 weeks long and represented three main parts, including a structured education of patients, bi-weekly follow-ups via telephone, and a systematic monitoring system of adverse events through provision of standardized toxicity grading criteria.

3.1 Layered Patient Education Programs

All participants were given a common patient education at the beginning of the therapy programming with the use of a clinical pharmacist. They were conducted based on the doctor-prescribed regimen of oral chemotherapy, which was mainly capecitabine or palbociclib, and covered guidelines on tapering schedules, food interactions, pill administration, storage and possible side effects.

Education materials were offered both in written and verbal form, and adapted to the literacy levels and language preferences. In India, the modules proved to have visual aids and translated hand outs in South Africa, and digital materials in Switzerland were availed to support the learning. The entire sessions were conducted within the privacy settings with the provision of confidentiality and encouragement of open discussions between the patient and the pharmacist.(6)

The learning units focused on the identification and self-management of early side effects, methods that could be used to prevent missed doses, and adherence besides the necessity of adherence to attaining treatment objectives. Patients were also taught to utilize a personal medication logbook in which they could count the doses or track the symptoms and missed medications, which made it easier to observe during follow-up.

3.2 Telephonic Follow-Ups to be conducted bi-Weekly

The pharmacists performed follow-up calls every two weeks after the initial education was provided to evaluate adherence, remind about the most important procedures and discuss appeared concerns. Calls were about 15-20

minutes and used a semi-structured checklist based on medication intake, side effects, missed doses and psychological wellbeing.

This telephone aspect provided sustainability in terms of interaction especially among the patients who had little access to face-to-face consultation. In India and South Africa, which had difficulty with transportation to the oncology clinics, these calls became an essential contact point to keep the continuity of care. Secure video sessions replaced some calls in Switzerland, this was depending on the preferences of the patient.

The follow ups were also used as an early warning survey of the negative events. In case that a moderate or severe symptom was reported, pharmacists informed the oncology care team about considering dose adjustment or judicious care activities. This would decrease treatment interruptions and visits to the emergency.

3.3 Toxicity grading and Adverse Effects Monitoring

During the follow-up calls, the adverse effects were recorded systematically along with the clinic visits which were scheduled as appropriate using Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0. Evaluation of the degree of symptoms and its classification in grades (1 to 5) were made by pharmacists, which was implemented in time to make clinical decisions.

Patients were prevented through education to recognise common toxicities that included hand-foot, diarrhoea/groups, exhaustion and neutropenia. They were advised to make any changes as soon as they noticed and either in form of regular calls, or through a special phone line.

This formal grading of toxicity allowed uniform documentation at all three centers and also could give real time data to alter doses, hold therapy or add lab surveillance. It has also allowed the research team to determine the associations between pharmacist, involvement and the occurrence of Grade 3 and above toxicities among the study population.(7)

4. Multicentral implementation framework

The study was carried out in three socioeconomically and geographically different centers of oncology in Switzerland, India and South Africa. All the centers helped in the core design, as well as the local tailoring of the pharmacist-led adherence intervention, and allowed testing the feasibility and effectiveness in different healthcare settings. Although the three elements of the intervention, that is, patient education, bi-weekly follow-up, and toxicity monitoring were standardized, their application was adapted to consider the availability of resources, level of literacy of the patients, and the existing infrastructure in each site.

4.1 Switzerland based Oncology Center

Swiss center: a tertiary care hospital of the University of Zurich, Switzerland, was a high-resource oncology arena, including pharmacy services and electronic health records (EHRs). Pharmacists at this center were also included in the multidisciplinary care management team and regularly attended the tumor boards and would participate in patient counseling sessions.

Introducing the adherence program in Zurich was not that hard because there already was the available structure of clinical pharmacy. The meetings of patient education took place in special rooms with counseling and follow-up message exchange took place through secure video conference, phone or encrypted patient portal. Patients were supplied with medication logs as printouts as well as through an app adapted on smartphones within the category of oncology. The information about adverse events was also inserted into the EHR system of the hospital and could be monitored by both oncologists and pharmacists in real time.

High digital literate patients were recruited in Switzerland, and most of them were pleased with the convenience of remote follow-ups and tracking methods using apps. Medication reconciliation was also done every time at the clinic visit by the pharmacists and this helped in consistent monitoring of polypharmacy and comorbidities.(8)

4.2 Oncology Center, India

The Indian site was a branch of a government-sponsored cancer hospital in Mumbai that provides a mixed-resource setting in terms of a large number of patients and PC per-patient ratios. Clinical pharmacy was a new concept and their main stress was on clinical and dispensing duties of oncology pharmacists.

To cater to the nature of various patients, educational sessions were being held in the local languages with the help of translated handouts and visual tools. All follow-ups were done on mobile phone only with modifications in the case of low-literate patients or those who share phones with their family members. Medication calendars printed with pictograms were also given in order to better comprehend the dosage frequency and treatment plans.

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Because of many constraints on digital environment, the paper-based grading of toxicity and toxicity adherence was completed, and subsequently scanned by the research team. Nevertheless, such limitations were compensated by high rates of patient engagement and the program reception. The intervention process facilitated by the pharmacist assisted in ensuring epistemic barriers between patients and the oncology team were overcome especially when adverse effects arose in the intervals between visits.

4.3 Oncology Center South Africa

South African site was a regional cancer center in Cape Town, which worked within a resource-limited system of public health but had preexisting partnerships with the schools of pharmacy and non-governmental organizations (NGOs). Pharmacy interns and community health workers who had been trained to engage patients accompanied the pharmacists in conducting the education sessions.

Simple dose charts formed part of the adherence tools and follow-ups were performed over voice calls and SMS depending on the patient preference and access to a phone. A modified CTCAE checklist was translated into patient friendly terms wherever adverse event reporting was needed.

The intervention was very effective especially in enhancing compliance of patients who had low health literacy despite the complication of fixing this logistically. Insourcing support staff and using less-sophisticated tools were highlights of the flexibility of the program within low-resourced environments.(9)

5. Assessment and Results

In order to determine the effectiveness of the intervention by clinical pharmacist on adherence and safety rates among the breast cancer patients receiving oral chemotherapy as treatment, the current study combined different validated measures of adherence, pharmacy usage records, and clinical events monitoring. Such assessment methods not only yielded subjective and objective data on the impact of pharmacist participation on the behavior and outcome of a patient throughout the 12 weeks study but also revealed the degree of success or failure of the overall implementation.

5.1 MMAS-8 Use

The primary tool, based on self-reports of adherence was the Morisky Medication Adherence Scale (MMAS-8). The questionnaire consists of 8 items, is consistently validated and measures how someone takes medication quantitatively with recollection, deliberate omissions and regularity of habit. Both the patients were asked to answer the MMAS-8 survey at baseline (week 0) as well as the conclusion of the study (week 12), and their scores were also assigned to represent either low (scale not exceeding 5), medium (6--7), or high (8) adherence.

MMAS-8: The MMAS-8 was completed face-to-face at baseline counseling and during follow-ups either over the phone or face-to-face at week 12. India and South Africa applied translations in order to guarantee understanding, whereas patients with low ability to read and write were given assisted completion through the pharmacist instructions. This permitted standardization of, but accessible benchmarking of, adherence scores across varied population.(10)

The scale was used as not only the outcome measure but also as the tool of education. Awareness on MMAS-8 responses assisted pharmacists in establishing the identification of adherence barriers and nullifying the misconceptions, on the go.

5.2 Data Analysis Pharmacy Refill

To objectively measure the results that were obtained in the MMAS-8 and in order to support the findings, the number of refills by each subject in a pharmacy was observed. Medication Possession Ratio (MPR) was determined by the ratio between the number of days of supply of medication dispensed to the number of days in the observation period. Patients that had an MPR 80% or more were regarded as compliant.

Data regarding refills were obtained at the outpatient pharmacies in the hospital belonging to every study site. Switzerland was another country in which there was the possibility of automated retrieval by way of digital pharmacies and on real-time basis. The manual dispensing logs in India and South Africa were reviewed and the duration of refills was estimated.

The complementary use of MMAS-8 and MPR analysis made sure the results were balanced as pertaining both to the adherence to behavioral aspects and access factors. Instances in which the MMAS-8 yielded a high adherence score, and yet there was less than optimal performance on the MPR, frequently represented systemic impediments, e.g., stock delays or travel concerns, but were potentially helpful pieces of information on how to modify the intervention in the future.

5.3 Clinical Outcomes: Hospitalization rate and Toxicity Rate

Presence and severity of chemotherapy-related toxicities and hospital admissions owing to adverse events were monitored in order to assess safety and tolerability. Follow-ups by means of phone calls, as well as clinic surveillance, was employed to grade toxicities according to the Common Terminology Criteria for Adverse Events Version 5.0 (CTCAE v5.0).(11)

Aside from hematopoiesis, grade 3 or higher toxicities, primarily neutropenia, diarrhea and hand-foot syndrome, were of particular concern, since they commonly result in dose interruptions or discontinuations. Any unexpected admission due to the complication of the treatment was monitored in terms of hospitalization.

Implementing the clinical pharmacist into early symptom recognition and education should decrease the level and occurrence of the treatment-related problems. Before the intervention, baseline incidence rates were compared (data gathered retrospectively on patient records) with the study period (12 weeks).

The combination of these outcome measures was able to give an overall perspective with regards to how the clinical pharmacist interventions enhanced adherence and reduced the risk associated with treatment, and this proved the worth of having the pharmacist in the oral management of the chemotherapy.

6. Results

6.1 Increase in Adherence Score

Also after the 12-week pharmacist intervention of the program, there was a statistically significant increase in patient adherence to oral chemotherapy regimens. As indicated by the MMAS-8 scores, it was found that the percentage of patients to receive high adherence (score 8) has risen by 32 percent at the baseline to 54 percent by the end of the intervention. In the meantime, the proportion of low adherence patients (<=5) decreased in number as recorded between 29 to 11 percent.

The average MMAS-8 score increased by 22 percent (p<0.001), with the largest improvements being observed in patients located in India and South Africa where baseline adherence was lower as compared to the other countries. Pharmacy refill numbers reinforced this remedy as the average Medication Possession Ratio (MPR) improved presently at 74 percent to 89 percent of the cohort. By the end of the research, the participants exceeding the 80% mark of MPR comprised more than 80%.

These observations indicate the superiority of the architectural education of pharmacists and tracking their subsequent activities in establishing favorable outcomes on medication-taking behavior, even in low-resource settings.

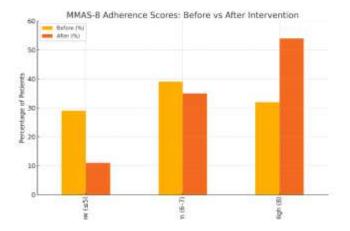


Figure 1: MMAS-8 Adherence Scores before and after the pharmacist-led intervention

6.2 Decrease in Serious Adverse Occurrence

There was a similar reduction in treatment-related toxicities in the study in their frequency and severity. The frequency of Grade \geq adverse events, which were recorded as grade using CTCAE v5.0, dropped to 15% after treatment in comparison to the 27% of people who experienced the adverse events at baseline. Differentially, there were less cases of hospitalization due to some of the preventable side effects such as neutropenia and gastrointestinal toxicity.

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The patients who were administered capecitabine experienced reduced occurrences of hand-foot syndrome and mucositis, which could be attributed to symptoms that were easily identified and action taken in response to direct interventions by the pharmacists. Patients in India and South Africa did not readily report side effects until late in the study, so putative cases of late-stage toxicity decreased substantially after pharmacist-monitored use of the drugs.(12)

In the three centers, pharmacist communication was used as an early warning system, making possible quick triaging, dose adjustments, or initiation of palliative care in order to stop the issue before it progressed. These resulted in the improved tolerability and treatment continuity that was a form of proactive adverse event management.

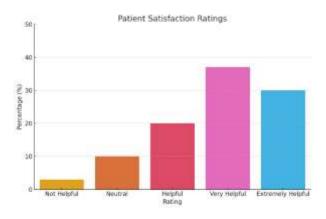


Figure 2: Patient Satisfaction Ratings across all centers

6.3 Results in satisfaction of patients

With respect to patient satisfaction with the intervention, the quality of the patient was also addressed by a structured 5-point Likert scale survey administered at week 12, in addition to adherence and clinical safety. Comprehensively, 87 percent of them tagged the program as either incredibly or very useful in helping them with their treatment.

Factors that were most important in influencing satisfaction were:

- Explicitness and understandability of pharmacist descriptions.
- Provision of timely assistance in the event of bad incidences.
- The empowerment and a feeling of control of their own therapy.

The feedback was especially encouraging when it comes to patients who never received one-on-one counseling prior. Numerous people appreciated the style of communication exhibited by pharmacists as one that showed understanding and built trust. In a place like South Africa where language barrier is largely a problem, participants appreciated multilingual teaching resources and the use of patient-friendly terms during consultations.

Net promoter score (NPS) of the pharmacist-led program that is measured by conducting the questionnaire is equal to +72, which characterizes robust interest in the willingness of patients to receive the continued involvement of pharmacists in their cancer management. These results are significant in justifying integration of clinical pharmacy service as a common component of outpatient oral chemotherapy program.

7. Conclusion

7.1 Summaries of Findings

This multicenter interventional trial proved that the structured, pharmacist-led interventional programs defining the adherence can be very largely helpful clinically and in terms of expanding participation of patients taking oral chemotherapy against breast cancer. This program was adopted in three different cancer care centers in Switzerland, India and South Africa and had a combination of standardised patient education, phone-based checkups twice a week and monitoring of adverse effects in real time with the help of grading according to CTCAE. Intervention had also resulted in a 22 percent improvement on MMAS-8 adherence scores, Increment to pharmacy refill consistency (MPR 80%) and significant reduction of Grade 3 or above toxicities. The problem is that the

number of hospitalizations caused because of the preventable adverse events also reduced, the rate of the patient satisfaction was extremely positive, and the pharmacist support was estimated on the 87% level as either of the following, namely, very helpful or subjected to the higher rank. All these findings point to the importance of clinical pharmacists as one of the most important players in the optimization of oral chemotherapy regimens, in out patient care settings as well as in home based care delivery systems.

7.2 Oncology Pharmacy Practice Implications

The results support the emerging trend of oncology pharmacists as a component of the cancer care team, especially at the facility in which patients are responsible in continuing their medications at the house. Convenient Oral chemotherapy needs people to follow sophisticated dosage schemes, learn the signs and symptoms of toxicity, and then decide on providing treatment on time, without always being able to have a clinician overseeing the treatment. Pharmacist-led interventions will solve these problems by providing sustained, individualized assistance outside of the clinic. This paper shows convincingly that proactive pharmaceutical care is highly effective in increasing adherence in addition to increasing patient satisfaction and safety. Such results are especially valuable in resource-limited environments, including the situation in South Africa and India, proving that even comparatively small interventions, like structured phone calls and educational tools can provide clinical benefits in large compound. In addition, the study provides evidence of the flexibility of pharmacist-led programs in various healthcare systems. Contextualizing of educational information, the means of communication, and toxicity monitoring tools allowed introducing high-impact care by the pharmacists, despite the technological or infrastructural drawbacks. Such flexibility is critical to wider scalability and evolution into national cancer care processes.

7.3 Suggestions regarding Broader Adoption

The success of pharmacist-led oral chemotherapy programs can be determined based on positive outcomes and some of the recommendations to extend it include:

Make clinical pharmacy positions institutionalized in the oncology unit in order to have pharmacists regularly assist in counseling the patients, providing follow-up, and toxicities.

Standardize oral chemotherapy modules and follow up procedures at cancer centers and adaptation of language, literacy and culture.

Use digital tools (e.g., mobile apps, text messaging, SMS) to track adherence and communicate with patients (e.g., in remote locations or underserved populations).

Train pharmacists and interns on medication related aspects of communication and triaging side-effects related to oncology to facilitate scalability in highly resource-restrained and unrestricted locations.

Help promote policy and funding of pharmacist services as reimbursable element of comprehensive cancer care. Finally, this paper supports a change in the support of oral chemotherapy not only as a prescription service but as a collaborative care process of therapy where clinical pharmacists play the lead and unending role.

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Conflicts of interest

The authors have no conflicts of interest to declare

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